



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/597,015

07/06/2006

John Colyer

9052-246

4772

20792 7590 09/17/2009
MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER

CHEU, CHANGHWA J

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

09/17/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/597,015	Applicant(s) COLYER, JOHN	
	Examiner JACOB CHEU	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-52, 54 and 57 is/are pending in the application.
- 4a) Of the above claim(s) 31-52 and 54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30 and 57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Applicant's amendment filed on 7/2/2009 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

Claims 1-29, 53, 55-56 have been cancelled.

Claims 30-52, 54 and 57 are pending.

Currently, claims 30 and 57 are under examination. Claims 31-52 and 54 are withdrawn from further consideration.

2. The "use claim" rejection under 35 U.S.C. 101 is moot since Applicant has cancelled this claim.

3. The rejections on claims 1, and 57 under 35 U.S.C. 102(b) as being anticipated by Blau et al. (WO 98/44350) are withdrawn because detection of the interaction of the target moiety with the binding partner is achieved by the parallel recognition of the scaffold material by its specific binding partner and there is no covalent bound between the scaffold material and the target moiety.

4. The rejections on claims 57 rejected under 35 U.S.C. 102(e) as being anticipated by Leyland-Jones et al.(US 20030091975) are withdrawn because there is no covalent binding between the target moiety and the scaffold material.

5. The rejections on claims 57 under 35 U.S.C. 102(b) as being anticipated by Abbott et al. (US 4521521) are withdrawn because the scaffold materials in Abbott et al. are polymer particles and do not have the controllable properties.

Art Unit: 1641

6. The rejections on claim 57 under 35 U.S.C. 102(e) as being anticipated by Upmeier et al. (US 20040137425) are withdrawn because Upmeier et al. use covalently cross-linked protein specific for an analyte, not a scaffold material covalently linked to a target moiety.
7. The rejections on claim 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Ideker et al. (US 20020107640) are withdrawn because the scaffold materials used by Ideker do not have the recited controllable properties.
8. The rejections on claim 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Caras et al. (US 5798448) **are maintained** (See below).
9. The rejections on claim 30 under 35 U.S.C. 103(a) as being unpatentable over Caras et al, in view of Zuk et al. (US 420847) **are maintained**. (see below).

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. The rejection on claim 57 rejected under 35 U.S.C. 102(b) as being anticipated by Caras et al. (US 5798448) is **maintained**.

Caras et al. teach covalently binding of CD4-IgG (target moiety) or (REK-7-IgG) with scaffold materials (protein A) in an immunoaffinity column (See Example 5) to purify REK7 ligand from BT20 cells. It is noted that the protein A is for purification purpose and would not interact with the REK7 ligand.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1641

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claim 30 rejected under 35 U.S.C. 103(a) as being unpatentable over Caras et al. in view of Zuk et al. (US 420847) is **maintained**.

With respect to “kit”, Caras et al. do not explicitly teaches a kit comprising the elements recited in claim 57. Zuk et al. teach that in performing assays, it is convenient and to combine the necessary reagents together in a kit (column 22, lines 20-35). Zuk et al. further teach that this may improve assay accuracy.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art to have motivated Caras et al. to place the covalently bound target-moiety with the scaffold material together as a kit for convenience and accuracy as taught by Zuk et al..

Response to Applicant's Arguments

Caras et al. reference

4. Applicant argues that:

“Caras et al. describe target moiety-scaffold fusions in which an IgG based scaffold is recognized by and bound to a protein A partner (example 5). This partnership is then covalently cross-linked. In embodiments of the present invention, it is noted that the scaffold material does not interact with any binding partners.” (see Remarks, page 3, last paragraph to first paragraph of page 4)(emphasis added).

Applicant's arguments have been considered, but are not persuasive.

First, the assertion of “the scaffold material does not interact with any binding partners” is not reflected in the claim language. The claim language merely recites “wherein the at least one domain of the scaffold is non-reactive to a binding partner specific to said target moiety or part thereof”. The so-called “scaffold material does not interact with any binding partner” is not consistent with the claim language. Second, the protein A in Caras et al. reference does not interact with the binding partner REK7 ligand, it is merely used in purification process.

Conclusion

5. No claim is allowed.
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1641

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACOB CHEU whose telephone number is (571)272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacob Cheu/

Examiner, Art Unit 1641